# 0.0 Table of Contents

# 0.1 Quality Policy Statement

## Quality Policy

U.S. Army Medical Research Acquisition Activity (USAMRAA) is committed to continuous improvement, striving to learn and exceed the expectations of our customers at all times.

As the Director of USAMRAA, I affirm this commitment and have established a system of total quality management in accordance with ISO 9001: 2000. We are committed, without exception, to continuous improvement, relentlessly seeking to learn the expectations of our customers and striving to exceed those expectations at every juncture. These efforts will enable us to accomplish the following goals:

1. Provide high quality, timely, customer-focused contracting guidance and acquisition solutions.
2. Provide the customers, both core and non-core, these quality products in support of their global U.S. military missions and national medical research interests.
3. Provide our staff an environment that fosters growth and well being.
4. Provide the community an atmosphere that instills public trust and demonstrates good citizenship.

The entire USAMRAA team will adhere to the policies, procedures, spirit and intent of our quality management and quality assurance systems. We all shall continue to aggressively strive to ensure that customer satisfaction and continuous process improvement are achieved at all times, and in everything we do.

Achieving high quality standards is part of our mission. It is our promise to our customers, to our employees and to our community. We are USAMRAA. We are Excellence in Acquisition.

_____

Kenneth B. Connolly
Director

# 0.2 Company Background

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is the acquisition and assistance solutions arm of the U.S. Army Medical Research and Materiel Command (USAMRMC). We are located at Fort Detrick in Frederick, Maryland. USAMRMC is a subordinate command of the Army Medical Command, located in San Antonio, Texas.

The USAMRAA staff consists mainly of contracting professionals in the Office of Personnel Management (OPM) designated 1102 series. In executing the mission set forth below, USAMRAA personnel solicit, negotiate, award, and administer contracts and assistance agreements in support of a broad spectrum of services, materiel, and research and development efforts. USAMRAA is the conduit through which USAMRMC's demand for goods and services are met.

**MISSION**

The U.S. Army Medical Research Acquisition Activity provides the following:

a. Quality, timely, and cost effective business advice and solutions for our customers and other stakeholders,
b. Respect, personal growth and well being to ourselves, and
c. Public trust and good citizenship for our community.

**VISION STATEMENT**

It is USAMRAA's vision to be the most effective acquisition activity in providing relevant, high quality, and timely business solutions for our customers.

## 0.3 Amendment Record

This Quality Procedures Manual (QPM) contains only the pages issued by this facility. The Management Representative (MR) will process all authorized changes, inserting amendment pages into the official distribution copies. The MR will see that all down level and/or obsolete pages are withdrawn from use and disposed of to prevent unintentional usage. The QPM is a controlled copy document. The MR maintains the master copy (MC) of the QPM. This MC shall be used as the final authority, regarding the latest revision level and amendment status for the USAMRAA QPM.

| Issue # | Section/s | Date | Page | Description of revisions | Approval |
|---|---|---|---|---|---|
| #1 | All | 02/10/00 | All | Release Draft Quality Assurance Manual | |
| #2 | All | 03/14/00 | All | Revision of QPM | |
| #3 | All | 05/22/00 | All | Revision of QPM | |
| #4 | All | 06/06/00 | All | Revision of QPM | |
| #5 | All | 06/09/00 | All | Revision of QPM | |
| #6 | All | 12/04/00 | All | Revision of QPM | |
| #7 | All | 07/09/01 | All | Revision of QPM | |
| #8 | All | 08/03/01 | All | Revision of QPM | |
| #9 | All | 08/05/02 | All | Revision of QPM | |
| #10 | All | 11/04/02 | All | Complete revision of QPM ISO 9001: 2000 | |
| #11 | All | 01/27/03 | All | Revision of QPM | |
| #12 | All | 06/20/03 | All | Revision of QPM | |

# QP4-1
# Control of Documents Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 4 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/ MR, the Deputy for Business Operations, the Chief, Business Oversight Branch, the Chief, Policy and Quality Assurance Branch**,** and the Deputy for Business Support (for administrative documents) have the responsibility and authority for implementing the requirements of this procedure. (NOTE: Policy documents are of a technical nature. Administrative documents relate to personnel and financial activities.)

## 3.0 PROCEDURE

3.1 All controlled documents are listed either on the electronic data base, on a master document list, or in a master document book.

3.1.1 Newly created forms or changes to forms are coordinated through the Forms Control Officer and with the Information Management Office to be entered into the system.

3.1.2 Forms that are kept electronically are write-protected. Only authorized individuals can make changes or add forms to the system. Those managers of the areas that use the document have review and approval authority.

3.1.3 Forms that are not kept electronically have some method of control such as revision date, revision number, etc.

3.1.4 The on-line forms list and a master forms list allow individuals to ensure they are using the most current version of documents.

3.1.5 All documents and data are controlled once the appropriate authorities review and approve them. The record of the review and approval is kept on an email, memo, or other positive method.

3.1.6 The revision status of the Quality Manual and Quality Procedures Manual can be verified by comparing the issue number or date to the issue number or date listed in the respective manual's amendment record.

3.1.7 The original Quality Manual and Quality Procedures Manual exist in hardcopy and electronically. The Management Representative is responsible for distributing any changes to these manuals.

3.1.7.1 Both of these manuals are available to all employees on the USAMRAA Homepage, thus eliminating the need for a controlled circulation list for hardcopies. A revised copy of the manual's amendment record must accompany the change that is distributed. The Management Representative is also responsible for retrieving any superseded documents and destroying them.

3.1.8 Quality forms will show the revision status information, (i.e. a revision level or revision date) if possible.

3.1.9 External documents (e.g., FARs) are controlled via the internet.

3.1.10 The Director's Office maintains an Administrative Document Master List.

3.1.11 All hard copy policy volumes are for reference only and are labeled as such. There are two ways of accessing policy documents electronically. The army website is updated on a daily basis. Information is also available on CD and is updated quarterly. USAMRAA requires all personnel, when in-house, to only pull information from the web. Information from the web is updated daily. Anyone using the CD acknowledges that this information is for reference only.

3.2 Document and Data Changes

3.2.1 The Deputy for Business Management, the Deputy for Business Operations, the Chief, Business Oversight, or the Chief, Policy and Quality Assurance Branch is responsible for pulling obsolete copies of policy documents and replacing them with the current revisions should these documents exist in hardcopy format. The Deputy for Business Support is responsible for pulling obsolete copies of administrative documents and replacing them with the current versions.

3.2.2 Obsolete on-line documents are segregated to an archive file or purged out of the system. Hard copy obsolete documents must be marked obsolete if they are not purged.

3.2.3 Whenever possible, the nature of a document change is indicated through the issuance of a memorandum by the responsible authority summarizing the changes and an attachment of the final revisions.

3.3 The Deputy for Business Management/ MR is responsible for ensuring that logos and accreditation marks are controlled/ displayed in accordance with the Command Regulation and PJR, Inc. Registration Mark Procedure.

## 4.0 RELATED DOCUMENTATION

Document Master List
USAMRMC Regulation 25-30-1 dtd 28 Jan 2000
Perry Johnson Registration Mark Procedure – PRO-3 dtd Jun 2000

# QP4-2
# Control of Records Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 4 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/ MR and Deputy for Business Operations have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 USAMRAA maintains the quality records mandated by ISO 9001: 2000 that are applicable to its operations. The Master List of Quality Records clearly details which record-keeping requirements are applicable including the record storage locations and the record retention periods.

3.2 Hard copies of quality records are stored in a manner that prevents damage, deterioration, or loss. The preferred storage method involves the use of file folders or binders.

3.3 The storage location that is listed on the Master List of Quality Records ensures that all quality records are easily retrievable and accessible to all necessary individuals. Procurement records are retained in accordance with MARKS System and FAR, depending on the type of contract. When space constraints are an issue then other hard copy records are stored off-site.

3.4 All hard copy records are clearly labeled to facilitate identification, indexing, and filing. The Army's MARKS system is used for labeling all official files.

3.5 All personnel are responsible for ensuring legibility of hard copy quality records.

3.6 Some quality records are stored electronically. Electronic back-ups are made daily to tape. These tapes are stored off site.

3.7 Designated closeout personnel are responsible for the destruction of quality records when their retention periods expire in accordance with the MARKS or taking these documents to the archive facility.

3.8 Master List of Quality Records:

| ISO Requirement | Identification | Storage | Protection | Retrieval | Retention | Disposition |
|---|---|---|---|---|---|---|
| Management review records (5.6.1) | Management Review Meeting Minutes | MR's office | Ordinary office environment | manual | 2 years min. | Ordinary trash/ recycle/ shred |
| Records of personnel qualification (6.2.2 e) | Certifications, tests, experience verifications, records of observations, etc. | CPAC and CPOC databases | Password protected | electronic | In accordance with MARKS | In accordance with MARKS |
| Process planning including customer-specific quality records (7.1 d) | Milestone Plan or Checklist Template | Award File | Ordinary office environment and/ or password protected (as appropriate) | manual and/ or electronic | 2 years min. | Records Holding |
| Requirements-for-product review (7.2.2) | Award File/ SPS/PD[2] | Award File | Ordinary office environment and/ or password protected (as appropriate) | manual and/ or electronic | 2 years min. | Records Holding |
| Internal audit records (8.2.2) | Internal Audit Checklists | MR's office | Ordinary office environment | manual | 2 years min. | Ordinary trash/ recycle/ shred |
| Inspection records (8.2.4) | Award File | Award File | Ordinary office environment and/ or password protected (as appropriate) | manual and/ or electronic | 2 years min. | Records Holding |
| Records of nonconformances (including any concessions) (8.3) | Corrective Action Report | MR's office | Ordinary office environment | manual | 2 years min. | Ordinary trash/ recycle/ shred |
| Corrective actions (8.5.2.e) | Corrective Action Report | MR's office | Ordinary office environment | manual | 2 years min. | Ordinary trash/ recycle/ shred |

| ISO Requirement | Identification | Storage | Protection | Retrieval | Retention | Disposition |
|---|---|---|---|---|---|---|
| Preventive actions (8.5.3.d) | Preventive Action Reports | MR's office | Ordinary office environment | manual | 2 years min. | Ordinary trash/ recycle/ burn |

## 4.0 RELATED DOCUMENTATION

Army Regulation 25-400-2 (The Modern Army Recordkeeping System (MARKS)

# QP5-1
# Management Responsibility Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 5 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

Top Management (i.e., the Director, the Deputy for Business Management/ MR, the Deputy for Business Operations, and the Deputy for Business Support) has the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

### Management Commitment

3.1 The evidence demonstrating Top Management's commitment to the development and implementation of the quality management system and continually improving its effectiveness is found in:

- 3.1.1 The Marketing Plan, which includes the importance of meeting customer as well as statutory and regulatory requirements.
- 3.1.2 The quality policy, as authorized by the Director.
- 3.1.3 Quality objectives, as outlined in the Balanced Scorecard.
- 3.1.4 Records of management reviews (which include resource issues).

### Quality Objectives

3.2 Quality objectives are established and recorded in the Balanced Scorecard.

### Responsibility and Authority

3.3 Responsibility and Authority are communicated through a variety of methods, including USAMRMC 10-1, work instructions, regulations, position descriptions, the Business and Marketing Plan, among other means.

**Management Representative**

3.4 The Director has appointed a member for management (i.e., the Deputy of Business Management) who, irrespective of other responsibilities, has responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

**Internal Communication**

3.5 Internal communication processes are outlined through a variety of methods, including work instructions, regulations, position descriptions, the Marketing Plan, among other means. Communication regarding the effectiveness of the quality management system is achieved through the management review process.

**Management Review**

3.6 Management Review Meetings are held at least on a quarterly basis, or more often as necessary.

3.7 The Management Representative and the Director are the only members of Top Management obliged to attend Management Reviews. Copies of the Management Review Meeting Minutes are distributed to, at minimum, the Deputy for Business Management (currently the Management Representative), Deputy for Business Operations, and Deputy for Business Support; the Director or Management Representative may distribute copies of the Minutes to other members of management his/their discretion.

3.7.1 During Management Reviews, the Management Representative reports to Top Management on the operation of the quality system, including:

3.7.1.1 Opportunities for improvement (see QP8-5 Improvement Procedure).

3.7.1.2 The quality objectives, which are established at relevant levels, measurable and consistent with the quality policy (see QP8-1 Monitoring and Measurement Procedure).

3.7.1.3 The quality policy.
3.7.1.4 Work Environment, Infrastructure, and Resources: buildings, workspace and associated utilities; process equipment, both hardware and software; and supporting services such as transport or communication in order to achieve conformity to service requirements; and the resources required to achieve quality objectives, enhance customer satisfaction, implement, maintain and continual improvement of the effectiveness of the quality management system.
3.7.1.5 Customer satisfaction and dissatisfaction feedback (see QP8-1 Monitoring and Measurement Procedure).
3.7.1.6 Follow-up on actions from previous management reviews.
3.7.1.7 Planned changes that could affect the quality management system and any steps required ensuring the integrity of the quality system is maintained.
3.7.1.8 The results of quality system audits.
3.7.1.9 Corrective actions, which indicate process performance and conformity.
3.7.1.10 Preventive actions.

3.8 The Management Representative maintains Management Review Meeting Minutes.
3.8.1 Management Review Meeting Minutes include any decisions and actions related to:
3.8.1.1 Improvement to the quality system and processes;
3.8.1.2 Improvement of product related to customer requirements; and
3.8.1.3 Resource needs.

## 4.0 RELATED DOCUMENTATION

Management Review Meeting Minutes
QP8-1 Improvement
Balanced Scorecard
Communications Plan

# QP6-1
# Competence, Awareness and Training Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 6 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Director, the Deputy for Business Management, the Deputy for Business Support, Deputy for Business Operations and the Customer Service Center Chiefs have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 Training requirements are very specific for acquisition positions. The Department of Defense (DoD) and the Department of the Army (DA) spell out these requirements. The Defense Acquisition University (DAU) publishes a list of training requirements each year for every career program as part of their catalog. The Customer Service Center Chief is responsible for monitoring all training requirements against the current mandatory standards.

3.2 Level 1 Certification is for people just entering their CAREER PROGRAM. They've taken the basic courses and have 1-2 years of experience in their field.

3.3 Level 2 Certification is the intermediate level. Advanced topics related to the primary career field are covered.

3.4 Level 3 Certification is the advanced level. All professional courses have been completed. Four positions at USAMRAA have been identified as Acquisition Corp positions. All must be Level 3 certified. This requires a detailed application procedure and independent review. All four positions are currently filled with qualified personnel.

3.5 Each employee maintains his/her own record of all the training they have received. Included in this may be copies of degrees, diplomas, and certificates earned. The individual employees are responsible for keeping track of the continuous learning points that they earn. The employees are

responsible for informing their supervisor of any training that has been received through the use of the IDP. The employee maintains his/her own Career Record Brief which is filed and maintained within an Acquisition Army-wide database.

3.6 Evaluation of the effectiveness of all training is carried out in the form of supervisor review on an annual basis.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures
Defense Acquisition University (DAU)

# QP7-1
# Planning Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 7 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Director, the Deputy for Business Management, the Deputy for Business Support and the Deputy for Business Operations have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 Prior to release, the Director, the Deputy for Business Management, the Deputy for Business Support and the Deputy for Business Operations review and determine specifications to ensure:

- 3.1.1 Quality objectives and requirements;
- 3.1.2 The need to establish processes, documents, and provides resources;
- 3.1.3 Required verification, validation, monitoring, inspection and test activities and the criteria for acceptance; and
- 3.1.4 Records needed to provide evidence that the realization processes and resulting awards fulfill requirements.

3.2 The output of planning is the Milestone Plan or the Checklist Template.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures
Milestone Plan (SPS/ $PD^2$ Manual)
Checklist Templates
USAMRAA Policy 03-01

# QP7-2
# Customer-Related Processes Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 7 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Operations, Deputy for Business Management, Deputy for Business Support and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 Purchase Requests (PR) are received electronically or hard copy in accordance with procedures set forth in USAMRMC Regulation 715-1, and the Account Manager Operational Notes. These documents form the initial records for the contract and agreement process.

3.2 Each PR is logged in and separated by customer. A contractor personnel assigned to IMO forwards the PR's by customers to the appropriate Customer Service Center. The Customer Service Center Chief assigns the PR to the appropriate Contract Specialist.

3.3 The Customer Service Center Chief, Account Manager or contract specialist reviews the purchase request and determines the appropriate purchase method and instrument negotiates the required changes and communicates results to all functional groups.

3.4 If additional information is needed, the Contract Specialist or Account Manager will contact the customer.

3.5 Checklists, manuals and other work instructions/regulations are used as appropriate, depending on the type of customer agreement being reviewed.

3.6 If the customer makes changes, the Account Manager or Contract Specialist involves the appropriate personnel to review the changes. If USAMRAA does not agree with the customer's changes, the Account Manager or the Contract Specialist contacts the customer for resolution.

All changes and resolutions are documented by the Account Manager or Contract Specialist and become part of the official file.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI)
SPS/ $PD^2$ Manual (Appendix C)
USAMRMC Regulation 715-1
AM Operational Notes

# QP7-4
# Purchasing Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 7 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Account Managers, Customer Service Center Chiefs, and Contract Specialists have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

### Evaluation of Vendors/Subcontractors

3.1 The Central Contractor Registry is available to all Customer Service Centers and serves as an equivalent to an Approved Vendor/Supplier List. However, each vendor/subcontractor is individually evaluated prior to being used.

3.2 Vendors/Subcontractors are not awarded a contract if they are not registered with the Central Contractor Registry.

3.3 Past Performance Information Management System (PPIMS) is maintained by the Army and is available on-line. Before awards are made, the PPIMS is checked when appropriate to ensure successful past performance of the selected vendor/subcontractor.

3.4 Vendors/Subcontractors are evaluated using the PPIMS system, when appropriate, as well as, monitoring non-conformances associated with vendors/subcontractors. Information in the system is used by the Army to help determine the continuing use of vendors/subcontractors.

3.5 The List of Parties Excluded from Federal Procurement and Non-Procurement Programs is checked, electronically or hard copy, to identify those parties listed (debarred) and the appropriate cause and treatment code determining a listed party's status.

3.6 The Defense Contract Audit Agency or other audit authorities will audit the records and facility of a vendor/subcontractor as requested by USAMRAA. Such reports are maintained by USAMRAA in the individual award files.

**Purchasing Information**

3.7 The Account Manager reviews and signs each award to signify approval. The award describes the product (supply, service or research and development) to be purchased, including where appropriate:
- 3.7.1 requirements for approval of product, procedures, processes and equipment,
- 3.7.2 requirements for qualification of personnel, and
- 3.7.3 quality management system requirements.

**Verification of Purchased Product**

3.8 Purchase requests are received electronically and/or hard copy. The Customer Service Center Chief, Account Manager or Contract Specialist reviews them for completeness. If incomplete, the customer is contacted verbally or electronically to resolve the issue. If unable to resolve, they are returned to the customer. If resolved, the AM/CS documents it for the official file. If customer corrects a returned PR, when corrected, it is returned to the AM/CS who made the finding.

3.9 On occasion, USAMRAA and/or the USAMRAA customer may verify purchased product at the vendor/subcontractor's premises. When this occurs, the intended verification arrangements are specified in the purchasing documents.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures
Approved Vendor/Supplier List
Vendor/ Subcontractor Evaluation Survey
Work Instruction/Regulations (FARS, DFARS, AFARS, DODGAR, AI,)
PPIMS Manuals
SPS/ $PD^2$ Manual (Appendix C)

# QP7-5
# Production and Service Provision Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 7 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/MR, Deputy for Business Operations, the Deputy for Business Support, Procurement Technicians, the Customer Service Center Chief, the Account Managers, and the Contract Specialists have the responsibility and authority for implementing the requirements of this procedure. The Chief Information Officer is responsible for oversight of the electronic systems needed to support the SPS/ $PD^2$/ ERMS requirements.

## 3.0 PROCEDURE

### Control of Service Provision

3.1 The USAMRAA is an acquisition office. USAMRAA conducts its core business through engaging in contractual and assistance relationships obtain products, services and research for customer/clients.

3.2 All employees are responsible for maintaining a safe and suitable work environment.

3.3 All contracting activities follow the same basic process:

- Receipt of Purchase Request
- Identify Program or Customer
- Review and assignment of Purchase Request
- Solicitation of Vendors/Subcontractors
- Award of contracts and/or Assistance Agreements
- Administration Review of Awards
- Final acceptance by customer
- Close out

3.3.1 Purchase requests are received, reviewed and assigned as per Customer Agreement Review (QP7-2 Customer-Related Processes).

3.3.2 Solicitation and awarding of the contract or assistance agreement takes place in accordance with various in-house and governmental regulations and instructions. These are found both in hard copy and on line. The regulations and instructions are updated and provided by the government, as they become available.

3.3.3 The guidelines provided in the Federal, Defense, Army and USAMRMC Regulations, Acquisitions Instructions and the DODGAR are followed to perform administrative actions.

3.3.4 Acceptance of product is done by the customer at the end of a contract and documented for close out.

3.4 Work instructions and quality forms are available and accessible.

3.5 The only equipment necessary for USAMRAA'S processes is the computer and other office equipment. This equipment is under a preventive system and is also maintained as needed. The Property Book Officer maintains location and maintenance records. There is an Information Management Office (IMO) that provides technical support services as needed.

**Product Identification and Traceability**

3.6 Files are identified according to the Army MARKS system, AR25-400-2 (1993).

3.6.1 When the designated representative for the Deputy of Business Management receives a PR, it is then forwarded to the Customer Service Center Chief who assigns the action to a Contract Specialist.

3.6.2 The Specialist gives the PR to the Procurement Technician to establish a file folder.

3.6.3 If the action will result in the award of an assistance agreement, the number is entered and traced in ERMS.

3.6.4 If the action will result in the award of a contract or an assistance agreement, the number is automatically assigned through SPS/ $PD^2$.

3.6.5 Where central files are maintained, the file is labeled in the following manner:

FILE LABEL: 715k DAMD17-_____
Contractor Name/Grantee Name

3.6.6 The File Cabinet is labeled in the following manner:
FILE CABINET LABEL: 715k Contract/Grant Actions
ACTIVE
PIF after final payment

3.6.7 Charge-out cards are available for placeholders when a file is removed from the file cabinet.

3.7 Nonconforming product or service is defined as a product or service that is not in compliance with Federal Acquisition Regulations, Department of Defense Federal Acquisition Regulation Supplement, the Army Federal Acquisition Regulation Supplement, and the Medical Research and Materiel Command's Acquisition Instruction or the DODGAR.

3.8 Hard copy contract files will be identified as nonconforming by affixing an appropriate identifier (usually a memo stating the non-conformity) and will be resolved in accordance with the Control of Nonconforming Product procedure.

3.9 Nonconforming electronic contract files will be identified by the attachment of a yellow note tab on the electronic version.

**Preservation of Product**

3.10 The Customer Service Center Chief, Account Managers and contract specialists ensure that hard copy contract files are handled with the utmost of care. Total electronic system files are backed up on a daily basis by the Information Management Office staff.

3.11 Contract files exist in either hard copy or electronic format or both. Hardcopy contract files are stored in file folders or binders and are kept in an environment that ensures their integrity for use. Electronic files are stored on official electronic media.

3.12 Hard copy files are labeled with the PIIN number and other identification according to the MARKS system. Electronic files are labeled with just the PIIN number but this PIIN can be traced to all other information.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures

AR 25-400-2 (1993**)**
Document Master List
SPS/ $PD^2$ Manual (Appendix C)
Work Instructions/Regulations (FAR, DFARS, AFARS, DODGAR, AI)

# QP8-1
# Monitoring and Measurement Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 8 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/ MR, the Deputy for Business Operations, the Deputy for Business Support, Customer Service Center Chiefs, Business Oversight Branch (Business Development Specialist), and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

### Customer Satisfaction

3.1 USAMRAA has established a Customer Survey Program that details the methods for how the organization monitors information relating to customer perception as to whether the organization has met customer requirements. The Plan includes both internal and external customers.

3.2 The Business Specialist analyzes the data and makes it available to the Management Representative, who presents the data during management reviews.

### Monitoring and Measurement of Processes and Product

3.3 Customer surveys are monitored weekly for customer feedback. Concerns are given to the functional manager for resolution. Follow up is provided to the customer by the functional manager. A quarterly roll up of the customer surveys is reported to the Director, Deputies, Chief, Policy & Quality Assurance Branch, and Chief, Business Oversight Branch.

## 4.0 RELATED DOCUMENTATION

Customer Survey Program/Customer Service Plan

.

# QP8-2
# Internal Audit Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 8 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/MR, the Lead Auditor, and the Internal Quality Audit Team have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 Deputy for Business Management/MR schedules internal quality audits on the basis of the status and importance of the activity to be audited. Deputy for Business Management/MR may choose to refer to the results of previous internal audits and the results of previous third party audits in order to schedule future internal quality audits. Thus, the audit schedule is a working document that is updated as necessary. The Deputy for Business Management/MR does ensure that all ISO 9001: 2000 elements are audited at least once a year.

3.2 All auditors have been trained in the ISO 9001: 2000 Standard by a qualified training contractor and are knowledgeable about basic audit theory. The Director then appoints auditors. The MR maintains copies of auditor appointments and training certificates. Auditors gather objective evidence through the following techniques: interviewing employees, reviewing documents, reviewing records, and observing activities and or processes.

3.3 In scheduling the audits, the Deputy for Business Management/MR ensures that personnel independent of those having direct responsibility for the activity being audited carry out internal quality audits.

3.4 The Deputy for Business Management/MR notifies the Deputies and Customer Service Center Chiefs of areas scheduled to be audited one week prior to the audit.

3.5 The selected members of the Internal Quality Audit Team use the USAMRAA Internal Quality Audit Checklist and the USAMRAA Form 61-R entitled USAMRAA Corrective Action Report/Opportunity for Improvement Report to record the audit findings.

3.6 At the conclusion of the audit, a closing meeting will be held to bring the audit findings to the attention of management personnel responsible.

3.7 If management disagrees with an audit finding, they may present evidence to the contrary to the Lead Auditor during the closing meeting. The Lead Auditor will review the objective evidence given, and make a final determination.

3.8 If it is determined that corrective action is needed, the auditee then has thirty days to decide upon the appropriate corrective action and a date by which the corrective action will be implemented. The suggested corrective action is recorded on the USAMRAA Corrective Action Report/Opportunity for Improvement Report and is submitted to the Lead Auditor for approval.

3.9 If the Lead Auditor accepts the suggested corrective action, then the auditee must implement it within the agreed to time period. If the Lead Auditor does not think that the corrective action is sufficient, then the auditee will have one additional week to devise an alternate corrective action. If the auditee requires additional time for implementing the corrective action, then they must gain permission from the Lead Auditor.

3.10 At the start of each audit the Lead Auditor is responsible for reviewing the Corrective Action Log for outstanding corrective actions and must follow-up on these as part of the regularly scheduled audit.

3.11 The next scheduled audit must then verify the implementation and effectiveness of corrective actions, as appropriate. At the start of each audit the Lead Auditor is responsible for reviewing the Corrective Action Log for outstanding corrective actions and must follow-up on these in addition to the regularly scheduled audit. Follow-up activities are recorded on the USAMRAA Corrective Action Report/Opportunity for Improvement Report. In order to complete the closeout process, the Lead Auditor must sign the Internal Quality Audit Form 61-R and enter the closeout date in the Lead Auditor's Corrective Action Log.

3.12 The MR must present the results of all internal quality audits at the next Management Review Meeting.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedure
QP8-5 Improvement Procedure
Document Master List

# QP8-3
# Control of Nonconforming Product Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 8 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Deputy for Business Management/MR, the Deputy for Business Operations, the Deputy for Business Support and the Account Managers have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 Nonconforming files are appropriately identified, but not segregated, because other parts of the process may continue that are unrelated to the breach of procedure.

3.2 Issues in everyday procedures are evaluated for severity. The Account Manager responsible for the acquisition action assesses the situation and determines the need for management involvement. Likewise, the Account Manager determines the applicability of the term "Nonconforming Product".

3.3 In the case of a breach of procedure, the Deputy for Business Management, the Deputy for Business Operations, the Deputy for Business Support, or the Account Managers must make a record of the Nonconformance. They send a written or electronic note to the individual responsible for correction relating to the action.

3.4 The person receiving the notice must conduct a root cause analysis and take action and document the correction. Depending on the nonconformance, they may also document a corrective action report as outlined in QP8-5 Improvement Procedure if it is a systemic problem.

3.5 After implementation of the action, the person who implemented the correction must notify the person who initiated the note or the nonconformity report. The Deputy for Business Operations, the Deputy for Business Management, the Deputy for Business Support, or the Account Managers, as appropriate, must verify the effectiveness of the

corrective action report and document the closeout activities. USAMRAA implements rework when correcting nonconformity.

3.6 Reworked contract files are always re-inspected in order to make sure that the breach of procedure related to the contract file has been remedied. Reworked product shall be re-inspected in accordance with the documented procedures.

3.7 In the case of the rework of a nonconformity related to either a Federal regulation or USAMRAA's procedures and instructions, the nature of the rework must be documented and is included as part of the hardcopy or electronic contract file.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures
QP8-5 Improvement Procedure
Document Master List

# QP8-4
# Analysis of Data Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 8 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Director, Deputy for Business Operations, the Deputy for Business Management, the Deputy for Business Support, and Contract Specialists have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

3.1 Top Management reviews and analyzes data relating to customer satisfaction in accordance with QP8-1 Monitoring and Measurement Procedure (Customer Satisfaction/Customer Survey) during Management Review Meetings.

3.2 Conformity to product/service requirements and characteristics and trends of processes and products including opportunities for preventive actions, which are reflected on Corrective Action Reports and Preventive Action Reports, are analyzed by Top Management during Management Review Meetings.

3.3 Vendor/Supplier performance is tracked via the Past Performance Information Management System. Contract Specialists analyze vendor/supplier performance on a project-by-project basis in accordance with established instructions and regulations and with QP7-4 Purchasing Procedure.

## 4.0 RELATED DOCUMENTATION

QP5-1 Management Responsibility Procedure
QP7-4 Purchasing Procedure
QP8-1 Monitoring and Measurement Procedure

# QP8-5
# Improvement Procedure

## 1.0 PURPOSE AND SCOPE

This procedure complies with the requirements of Section 8 of ISO 9001: 2000 as applicable to the quality management system.

## 2.0 RESPONSIBILITY AND AUTHORITY

The Director, Deputy for Business Operations, the Deputy for Business Management, and the Deputy for Business Support have the responsibility and authority for implementing the requirements of this procedure.

## 3.0 PROCEDURE

### Continual Improvement

3.1 Top Management develops continual improvement projects with the goal of improving the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

3.2 The inputs to continual improvement projects are primarily the PMR and the Quality Assurance Review Report. The output of continual improvement projects is the Balanced Scorecard.

### Corrective Action

3.3 When a complaint or concern is received, it is forwarded to the Director, Deputy for Business Management, the Deputy for Business Operations, or the Deputy for Business Support. The Director, the Deputy for Business Management, the Deputy for Business Operations, or the Deputy for Business Support retain the right to distinguish a valid customer complaint from one that stems from the customer's misunderstanding of their own requirements or unreasonable expectations.

3.4 The Director, the Deputy for Business Operations, the Deputy for Business Management, or the Deputy for Business Support are responsible for the follow-up of corrective action to make sure that the corrective action that was documented is, indeed, effective. The results will be documented and tracked in the Task Management System by the relative

Tasker Number, Action Officer or Task Title.

3.4.1 Corrective actions are also documented on the Corrective Action Report. The report reflects:

3.4.1.1 the review of nonconformances (including customer complaints,

3.4.1.2 the root cause analysis,

3.4.1.3 the evaluation of the need for action to ensure that nonconformances do not recur,

3.4.1.4 the determination and evidence of action the implementation of action needed,

3.4.1.5 the records of the results of action taken, and

3.4.1.6 the review of corrective action taken.

3.5 The Director, the Deputy for Business Operations, the Deputy for Business Management, or the Deputy for Business Support are responsible for monitoring the timeliness of assigned corrective actions. The Director, the Deputy for Business Management, the Deputy for Business Operations, and the Deputy for Business Support run reports for the corrective action that they assigned and the corrective actions for which their respective divisions are responsible**.** A search may be executed with the "Find" button by selecting the relative Tasker Number or Action Officer or Task Title.

**Preventive Action**

3.6 A preventive action process has been developed to detect potential non-conformities or to fix an opportunity for improvement before it becomes a nonconformance. The sources for this information are the Procurement Management Reviews (PMR), SPS/ $PD^2$, Extramural Research Management System (ERMS), Task Management System and review of previous Internal Audit Reports, customer complaints, customer surveys and quality records. The documented procedures controlling aspects of preventive action are as follows:

3.6.1 Appropriate sources of information mentioned above to detect, analyze and eliminate potential causes of nonconformity are utilized.

3.6.2 The preventive actions are initiated, tracked and effectively implemented through the Tasker System and on the Preventive Action Report, which reflects:

3.6.2.1 the determination of potential nonconformances and their causes,

3.6.2.2 the evaluation of the need for action to prevent occurrences of nonconformances,
3.6.2.3 the determination and evidence of action the implementation of action needed,
3.6.2.4 the records of the results of actions taken, and
3.6.2.5 the review of preventive actions taken.

3.6.3 Preventive actions are reported at Management Review Meetings.

3.6.4 The MR maintains records associated with preventive action.

**Reporting**

3.7 The Deputy for Business Management/MR is responsible for reporting the status of corrective and preventive actions at Management Review Meetings. Summary reports may be taken from the electronic system to facilitate this reporting.

## 4.0 RELATED DOCUMENTATION

QP4-2 Control of Records Procedures
Task Management System (Electronic)
Balanced Scorecard
Quality Assurance Review Report
Corrective Action/Opportunity for Improvement Report
Preventive Action Report